G3

Harmonize

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G3 (Activity 1)	More closely harmonize the inspection technique for conducting Quality System inspections with that used in the international community.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Industry responses to a multi-part question on a Customer Satisfaction Survey
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. The most responsible person at each of the inspected firms who was directly involved in the inspection will be mailed an OMB approved Customer Satisfaction Survey. They will be invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form will contain the multi-part question, "We designed QSIT to be closer to the Global Harmonization Guideline for Auditing Quality Systems. Did you find the QSIT approach similar to that used by auditing organizations utilized by your firm (i.e. Notified Bodies, third party assessors, internal auditing groups etc.)? Yes [ ] No [ ] No opinion or experience with this subject [ ] If yes, was this useful to your firm? Yes [ ] No [ ] Explain and provide examples of the similarities and usefulness." Responses will be tabulated and analyzed. Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332)	
Acceptance criteria (if known)	The majority of survey responses affirm that the QSIT approach is similar to that used by other auditing organizations. Also, the majority of survey responses affirm that having a similar approach is useful to firms.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity provides a direct and objective measurement on whether the QSIT approach is similar to that used by other auditing organizations. It does not directly compare QSIT to the current FDA auditing technique.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity allows firms (stakeholders) to provide input into the assessment of this goal.	

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G3	Increase the focus of the approach to conducting Quality System inspections on the key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.	
Activity #	**Type of activity** (test or analysis)	**Parameter(s)** to be measured
1	Test	Industry responses to a multi-part question on a Customer Satisfaction Survey
Acceptance Criteria	The majority of survey responses affirm that the QSIT approach is similar to that used by other auditing organizations. Also, the majority of survey responses affirm that having a similar approach is useful to firms.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study. Subsequent to the conclusion of the inspection, the most responsible person at each of the 42 inspected firms who was directly involved in the inspection was mailed an OMB approved Customer Satisfaction Survey. They were invited to voluntarily provide their views on the QSIT by completing and returning the survey form. The survey form contained the multi-part question: " We designed QSIT to be closer to the Global Harmonization Guideline for Auditing Quality Systems. Did you find the QSIT approach similar to that used by auditing organizations utilized by your firm (i.e. Notified Bodies, third party assessors, internal auditing groups etc.)? Yes [ ] No [ ] No opinion or experience with this subject [ ] If yes, was this useful to your firm? Yes [ ] No [ ] Explain and provide examples of the similarities and usefulness." A total of 19 (45%) industry responses were received. A tabulation of individual responses is attached. It was determined that 14 of the 19 firms found the QSIT approach similar to that used by auditing organizations they utilized. *(4 of the 19 responding firms had no opinion or experience with the subject, and 1 did not provide a specific answer. None of the firms stated the QSIT approach was not similar).* A total of 12 of those 14 firms stated the similar approach was useful. *(2 did not provide a specific answer. None of the firms stated the similar approach was not useful.)*	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

Item # G3 (Activity 1)

QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY question:

Part 1 We designed QSIT to be closer to the Global Harmonization Guideline for Auditing Quality Systems. Did you find the QSIT approach similar to that used by auditing organizations utilized by your firm (i.e. Notified Bodies, third party assessors, internal auditing groups etc.)? Yes [ ] No [ ] No Opinion or Experience with this subject [ ]

Part 2 If yes, was this useful to your firm? Yes [ ] No [ ]

Part 3 Explain and provide examples of the similarities and usefulness.

TABULATION of RESPONSES

PART 1				PART 2		PART 3
Form	Y	N	?	Y	N	Comment
1	X			X		Our Quality System is structured per the 20 sections of ISO 9001. We are not ISO 9001 certified as yet, but auditors that we have used performed audits very similar to the QSIT format – consistency.
2	X			X		Reduces confusion in establishing & maintaining the quality system
3	X			X		We are ISO 9001 certified. Allows us to standardize our approach to all processes and achieve full compliance for both ISO and the QSR.
4	X					I found the QSIT to be very similar to NB approach (e.g., Management Controls). Because of this similarity, it seems like the FDA could have used results from a NB to satisfy regular facility inspections.
5			X			
6						I preferred the FDA's approach to that taken by our ISO registrar. FDA was more process-oriented. Our ISO registrar spends a lot of time searching for minor mistakes in paperwork and asking for trivial changes to the QA manual & other documents.
7	X			X		Consistency in auditing style and approach.
8	X					We are a ISO 9001 company and our quality manual adapts very well with the QSIT.
9	X			X		Very similar to approach taken by third party assessors and our customers. This facilitates the audit process.
10			X			
11	X			X		The 4 areas targeted by QSIT closely parallel areas Notified Bodies target. Doc. is set up to easily highlight these areas and facilitates ease of communication.
12			X			
13	X			X		FDA spend time learning how systems work (not necessarily verifying the integrity of systems (or how they work) – Approach by FDA was similar to TUV.
14	X			X		Our external auditor that conducts an annual audit, used the QSIT approach. This helped us prepare for the FDA Audit format.
15			X			

PART 1				PART 2		
Form	Y	N	*	Y	N	Comment
16	X			X		Where the areas of the inspection were similar the expected results or perceived level of compliance was different. Other organizations audit to a level of determining whether procedures are in place. The FDA appears to audit compliance to a procedure.
17	X			X		Starting with Management review and starting each section with an overview of systems – both provided our staff with a familiar auditing process.
18	X			X		It makes it much easier to explain our quality system to the auditors/inspectors when there is a common focus.
19	X			X		The top down approach was similar to our Notified Body approach to auditing. The main difference between our last FDA inspection and our Notified body assessment is the amount of time out on the manufacturing floor. Out notified body spends more time looking at how systems work and the FDA inspector we had looked for documentation supporting the various systems, both valid approaches but still slightly different.

*No Opinion or Experience with this subject

TOTALS

Did you find the QSIT approach similar to that used by auditing organizations utilized by your firm (i.e. Notified Bodies, third party assessors, internal auditing groups etc.)?

Yes 14 No 0 No Opinion or Experience with this subject 4 (No response 1)

└──►If yes, was this useful to your firm?

Yes 12 No 0 (No response 2)

QSIT VALIDATION WORKSHEET

Item #	Goal/Outcome	
G3 (Activity 2)	More closely harmonize the inspection technique for conducting Quality System inspections with that used in the international community.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Comparison Analysis	QSIT compared to ISO Audits
Scope and nature of the process to be followed.[2]	Study will require co-operation of 3 - 4 notified bodies and at least 2 Competent Authorities. They will be asked to review QSIT format and give an analysis of how it compares with ISO audits. Use contacts from GHTF/SG-4 to approach notified bodies and competent authorities. Suggested notified bodies: TUV, BSI, Australia, Underwriters Laboratory (USA or UK); Suggested Competent Authorities: Medical Devices Agency (great Britain) and National Standards Authority of Ireland. A comparison worksheet document will be developed for use from the QSIT flowcharts. Proposed timeline for activities: Contact to solicit participants: By 2/16/99 Proposed initiation date: 3/5/99 (Ship QSIT materials and worksheets to participants) Proposed worksheet return dates: 4/23/99 Proposed completion date: 6/4/99 Responsibility for activity: Karen Coleman (HFR-SE150); CDRH/Tim Wells provide copies of QSIT Handbook, Federal Express Acct. Info: Chris Nelson and Georgia Layloff review and guidance ;	
Acceptance criteria (if known)		
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	Strengths: Identify similar areas that are harmonized Weakness: Differences may surface that cannot be harmonized and must be covered separately for FDA t meet their obligation under the law.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	Technique allows analysis of inspectional techniques with minimum expenditure of time and money.	

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[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome

QSIT Validation Activity Report

Item G3
Activity 2

This Activity was not completed.

MANAGEMENT CONTROL WORKSHEET

1. YES NO Does the auditor confirm that a quality policy, management review, quality audit procedures, quality plan and quality system procedures, and instructions have been defined and documented?

   1.1 Where are the reviews conducted? [select one of the following and write in the comment section below:] (1) Auditor's office; (2) At firm during the audit; (3) Both places

	Prior to Audit (check all that apply)	During the Audit	Comments:
Quality Policy			
Management Review			
Quality Plan			
Quality System Procedures			

2. YES NO Does the auditor confirm a quality policy has been implemented?

   2.1 How was this confirmed? Review of procedures Interview/s with employees Procedure reviews & Interviews; Other_____

3. YES NO Does the auditor review the firm's established organizational structure to confirm that it includes provisions for responsibilities, authorities, and necessary resources?

4. YES NO Does the auditor confirm that a management representative has been appointed.?

   4.1 Describe how the auditor evaluates the purview (authority) of the management representative?

5. YES NO Does the auditor confirm that management reviews include a review of the suitability and effectiveness of the quality system are being conducted?

   5.1 How was this confirmed? Review of procedures Interview/s with employees Procedure reviews & Interviews; Other_____

6. YES NO Does the auditor confirm that quality audits, including reaudits of deficient matters, of the quality system are being conducted.

   6.1 How was this confirmed? Review of procedures Interview/s with employees Procedure reviews & Interviews; Other_____

DESIGN CONTROL WORKSHEET

1. YES NO Would an auditor routinely select a single design project for review?

   1.1 If "NO" explain what your organization would do and why.

2. YES NO For the design project selected, does the auditor determine whether the auditee has design control procedures (addressing the requirements of ISO 9001 section 4.4) that have been defined and documented?

3. YES NO Does the auditor assure design & development planning activities include assigned responsibilities and interfaces.

4. YES NO Does the auditor evaluate the firm's conduct of risk analysis while proceeding through the assessment of the firm's Design Control system.

   4.1 If "NO" explain how your organization would evaluate risk analysis and why.

5. YES NO Does the auditor confirm that design inputs were established?

6. YES NO Does the auditor assure that design outputs that are essential for the proper functioning of the device are identified?

7. YES NO Does the auditor confirm that acceptance criteria are established prior to the performance of verification and validation activities?

8. YES NO Does the auditor review design verification activities to confirm that design outputs meet the design input requirements?

9. YES NO Does the auditor have to confirm that design validation data shows the approved design met the predetermined user needs and intended uses?

   9.1 If "YES" describe how this confirmation is made.

10. YES NO Does the review of the completed design validation assure the firm did not leave any unresolved discrepancies.

11. YES NO If the device contains software, does the auditor confirm that the software was validated?

12. YES NO Determine if design validation was accomplished using initial production devices or their equivalents?

13. YES NO Does the auditor confirm that changes were controlled including validation or where appropriate verified?

14. YES NO Does the auditor determine if design reviews were conducted?

14.1 If "YES" how were the reviews confirmed? Review of Procedures/Records
Interview/s with employees Procedure/records reviews & Interviews
Other_____

15. YES NO Does the auditor determine if the design was correctly transferred to production?

Corrective and Preventive Actions Worksheet
(CAPA)

1. How do auditors confirm that the CAPA system procedure(s) for the requirements of ISO 9001 section 4.14 have been defined and documented?

   Review of procedures Interview/s with employees Procedure reviews & Interviews

   Other _____

2. How does an auditor determine if appropriate sources of product and quality problems have been identified?

   Review of procedures Interview/s with employee's Procedure reviews & Interviews

   Other _____

3. YES NO Does the auditor confirm that data from these sources are analyzed to identify existing product and quality problems that may require corrective action?

4. YES NO If sources of product and quality information show unfavorable trends have been identified does the auditor confirm that data from these sources are analyzed to identify potential product and quality problems that may require preventive action?

   4.1 How does the auditor confirm that both corrective and preventative actions were performed?

5. YES NO Does the auditor challenge the quality data information system?

   5.1 Explain "how" the challenge was performed?

6. YES NO Does the auditor determine that the data received by the CAPA system are complete, accurate, and timely?

   6.1 How was the determination performed?

7. How does the auditor confirm that appropriate statistical methods are employed (where necessary) to detect recurring quality problems? [Other than check that there is a written procedure stating appropriate statistical methods will be used]

8. YES NO Does the auditor determine if results of analyses are compared across different data sources to identify and develop the extent of product and quality problems?

   If "No" why is this not done?

9. How does the auditor determine if failure investigation procedures are followed?

   Review of procedures Interview/s with employee's Procedure reviews & Interviews

   Other _____

10. How does an auditor determine if the degree to which a quality problem or non-conforming product is investigated is commensurate with the significance and risk of the non-conformity?

11. YES NO Does the auditor confirm that failure investigations were conducted to determine root cause (where possible)?

12. YES NO Does the auditor confirm that there is a control mechanism for preventing distribution of non-conforming product?

13. YES NO Does the auditor determine if appropriate actions have been taken for significant product and quality problems identified from data sources?

13.1 How is this determination made?

14 . YES NO Does the auditor determine if corrective and preventive actions were effective and verified or validated prior to implementation?

15. YES NO Does the auditor confirm that the firms' corrective and preventive actions did not adversely affect the finished device?

16. YES NO Does the auditor determine that corrective and preventive actions for product and quality problems were implemented and documented?

16.1 How is this verified? Review of procedure Interview/s with employees

Procedure reviews & Interviews; Other_____

17. YES NO Does the auditor determine if information regarding nonconforming product and quality problems and corrective and preventive actions has been properly disseminated, including dissemination for management review?

17.1 How is this determined? Review of procedures Interview/s with employees

Procedure reviews & Interviews: Other_____

Production and Process Controls Worksheet

1. QSIT instructs an investigator/auditor to evaluate production and process controls using the items in a list below.

Select a process for review based on: [If your auditor uses this item place a check mark (√) in the block to the right]

a. CAPA indicators of process problems;

b. Use of the process for manufacturing higher risk devices;

c. Degree of risk of the process to cause device failures;

d. The firm's lack of familiarity and experience with the process;

e. Use of the process in manufacturing multiple devices;

f. Variety in process technologies and product types;

g. Processes not covered during previous inspections;

h. Any other appropriate criterion as dictated by the assignment;

2. YES NO Does your system provide guidance on how to select a process for review?

3. YES NO Is the guidance similar to the QSIT guidance?

3.1 If "NO" explain in written text how an auditor makes this type of decision and what would be significant to your organization for guidance on covering this system?

4. YES NO Does the auditor review the specific procedure(s) for the manufacturing process selected and the methods for controlling and monitoring the process?

4.1 How does the auditor confirm that the process is controlled and monitored?

Data review Interview/s with employee's Data reviews & Interviews

Other _____

Note: Control and monitoring procedures may include in-process and/or finished device acceptance activities as well as environmental and contamination control measures.

5. YES NO If during the auditor's review of the Device History Records (including process control and monitoring records, etc.) they find the process is outside the firm's tolerance for operating parameters and/or rejects or that product nonconformances exist would they evaluate it?

Would the evaluation include any of the following?

5.1. YES NO Determining whether any nonconformances were handled appropriately?

5.2. YES NO Evaluating the validation study in full to determine whether the process has been adequately validated?

5.3. YES NO If the results of the process reviewed can not be fully verified, would the auditor confirm that the process was validated by reviewing the validation study?

5.4. YES NO If the process is software controlled, will the auditor confirm that the software was validated ?

5.5. YES NO Does the auditor routinely review and evaluate the software validation study?

5.6 Other _____

6. YES NO Does the auditor confirm that personnel have been appropriately qualified to implement validated processes or appropriately trained to implement processes which yield results that can be fully verified?

Sterilization Process Controls Worksheet

1. YES NO Does the auditor confirm that the sterilization process was validated by reviewing the validation study. If "NO" explain why this is not done.

2. YES NO Does the auditor review the specific procedure(s) for the sterilization process selected and the methods for controlling and monitoring the process

   2.1 How does the auditor confirm that the process is controlled and monitored?

   [check all that apply] Review of procedures Interview/s with employees

   Review of processing records Other_____

3. If review of the records (including process control and monitoring records, acceptance activity records, etc.) reveals that the sterilization process is outside the firm's tolerance for operating or performance parameters:

   3.1 YES NO Does the auditor determine whether the nonconformances were handled appropriately?; and

   3.2 YES NO Does the auditor review the equipment adjustment, calibration, and maintenance?

4. YES NO If the sterilization process is software controlled does the auditor confirm that the software was validated?

5. YES NO Does the auditor confirm that personnel have been appropriately qualified and trained to implement the sterilization process?

   5.1 How was this confirmed? [Check all that apply] Review of procedures

   Interview/s with employees Training record reviews

   Other_____